



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

Re: Aloxi  
Docket No.: 2004E-0394

The Honorable Jon Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

JAN - 6 2006

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,202,333, filed by Roche Palo Alto, LLC, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Aloxi, the human drug product claimed by the patent.

The total length of the regulatory review period for Aloxi is 3,867 days. Of this time, 3,565 days occurred during the testing phase and 302 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 24, 1992.

The applicant claims December 22, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 24, 1992, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 27, 2002.

FDA has verified the applicant's claim that the new drug application (NDA) for Aloxi (NDA 21-372) was initially submitted on September 27, 2002.

3. The date the application was approved: July 25, 2003.

FDA has verified the applicant's claim that NDA 21-372 was approved on July 25, 2003.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad

Associate Director for Policy  
Center for Drug Evaluation and Research

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